IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF KIMBERLY KENTON, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude the testimony of Kimberly Kenton, MD, MS, FACS, FACOG. (Doc. 2087).

INTRODUCTION

Dr. Kenton is a urogynecologist, internationally recognized as a leader in Female Pelvic Medicine & Reconstructive Surgery/Urogynecology. Plaintiffs' Motion Ex. D, March 1, 2016 Expert Report ("Expert Report") at 1 (Doc. 2087-5). She is board certified by both the American Boards of Obstetrics & Gynecology and Urology in Female Pelvic Medicine & Reconstructive Surgery and by the American Board of Obstetrics & Gynecology in Obstetrics & Gynecology. *Id.* She has extensive experience as a surgeon, educator, and researcher in her field. *Id.* at Ex. A to Expert Report, Curriculum Vitae. Dr. Kenton completed her fellowship in Female Pelvic Medicine & Reconstructive Surgery in 2002 and has since remained in the medical education field, serving in a variety of academic appointments. *Id.* Currently, she is Professor of Obstetrics/Gynecology and Urology, Division Chief of Female Pelvic Medicine & Reconstructive Surgery (FPMRS) at Northwestern University, Feinberg School of Medicine in

Chicago, Illinois. Expert Report at 1. She is a member of and has held leadership positions in many major professional associations, including the American Urogynecologic Society (AUGS), Society of Gynecologic Surgeons, American College of Obstetricians & Gynecologists, Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU), American Urologic Association, and others. *Id.* at 3.

Dr. Kenton has regularly performed surgery to treat stress urinary incontinence since beginning her fellowship in 1999. *Id.* at 4. She has performed a variety of procedures including Burch, bladder neck fascial slings, and synthetic mesh slings. *Id.* at 4-6. She has performed over 1,000 TVT and TVT Exact and 250 TVT-O procedures. *Id.* at 6. Her extensive experience in the field as a surgeon, educator, and researcher resulted in her leadership in national certifying and credentialing organizations. *Id.* at 2. For example, Dr. Kenton was selected by the American Boards of Obstetrics & Gynecology and Urology to serve on the joint Female Pelvic Medicine & Reconstructive Surgery division charged with developing the exam to certify surgeons in FPMRS. *Id.* Additionally, Dr. Kenton is an oral and written examiner for the American Board of Obstetrics & Gynecology FPMRS board certification, she serves on the scoring committee for the National Board of Medical Examiners, she has served on the Clinical Document Review Panel and Gynecology Practice Bulletin Committee for ACOG, she has served as the Education Committee Chair and member of the Board of Directors for AUGS, and the Research Committee and Systematic Review Group for SGS, and she worked to develop guidelines for fellowship training in FPMRS for the Accreditation Counsel of Graduate Medical Education. *Id.*

She also earned a Master of Science in Clinical Research Design and Statistical Analysis from the University of Michigan, Ann Arbor. *Id.* at 1. She has worked extensively participating

in and designing trials, including the largest US comparative effectiveness trial comparing Monarc and TVT-O transobturator midurethral slings to the gold standard TVT retropubic midurethral sling manufactured by Ethicon ("TOMUS Study"). *Id.* at 5. This TOMUS Study captured data relevant to safety and efficacy at 1, 2, and 5 years after surgery. *Id.* Dr. Kenton was also an investigator in a similar RCT comparing the Burch Colposuspension procedure to the Autologous Fascial Sling procedure ("SISTEr Study"). Plaintiffs' Motion Ex. B, September 15, 2015 Expert Report ("September Expert Report") at 5 (Doc. 2087-2).

In these cases, Dr. Kenton intends to offer opinions generally addressing the utility and safety of the TVT and TVT-O devices. Her opinions are based upon her education, medical training, clinical experience, extensive review of medical literature, participation in design, trial design and participation, experience educating and training others, practice and educational guidelines, and various other materials reflected in her reliance list. Expert Report; Ex. B to Expert Report, Reliance List. She is qualified to opine on these topics and, as detailed below, her opinions are supported by reliable methodology.

Plaintiffs have challenged certain aspects of Dr. Kenton's opinions, and as set forth below, Plaintiffs' arguments lack merit and should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

A. Dr. Kenton is qualified to offer opinions regarding the TVT and TVT-O devices, and her opinions are supported by reliable methodology.

Dr. Kenton is well qualified to testify about the safety and utility of the TVT device, and employed sound methodology using reliable data to support her opinions. The arguments offered by Plaintiffs to exclude her testimony on this issue are without merit, as detailed below.

1. Dr. Kenton is qualified to opine regarding the safety and efficacy of the TVT and TVT-O devices.

As described above, Dr. Kenton is a highly qualified urogynecologist with extensive experience as a surgeon, educator, and researcher. Nonetheless, Plaintiffs challenge Dr. Kenton's qualifications to opine about aspects of the TVT device's safety and efficacy that relate to physical properties of the device.[1] Plaintiffs rely solely on the argument that Dr. Kenton is not trained in chemical or structural engineering or biomechanics. This argument is misguided. This Court has previously found that a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify her to opine on "how the product reacts inside the body." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 18872222 (S.D.W. Va. Apr. 24, 2015); *see also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014), 2014 WL 5320566 (finding urogynecologist who has performed sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infections); *Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475, 2015 WL 1931311 (Apr. 28, 2015) (finding physician's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *Jones v. Bard, Inc.*, No. 2:11-cv-00114, at 6-9 (finding physician qualified to opine as to polypropylene and product design).

Specifically, Plaintiffs challenge twelve bullet-pointed opinions from Dr. Kenton's Report that Plaintiffs argue should be excluded because they are related to the design properties of the device. Plaintiffs' challenge to Dr. Kenton's qualifications fails. Like the physicians in

[1] Importantly, Plaintiffs have not and, indeed, cannot, challenge the sound methodology used by Dr. Kenton in forming each of the opinions objected to by Plaintiffs, only Dr. Kenton's qualifications. Each of the opinions is firmly grounded in Dr. Kenton's extensive clinical experience and review of relevant clinical data and literature.

cases cited above, Dr. Kenton is a skilled urogynecologist, with 17 years of experience surgically treating stress urinary incontinence. Expert Report at 4. It is difficult to credibly deride Dr. Kenton's qualifications generally. She has performed over 1,250 TVT, TVT-Exact, and TVT-O surgeries alone, in addition to surgeries using a variety of other synthetic and biologic materials. *Id.* at 4-6. She has participated in as well as designed, implemented, and published clinical studies on mesh products. *Id.* at 1,5; *see also* CV. Her opinions are premised upon a thorough understanding of the interaction of the body with permanent surgical implants, along with clinical observations from performing TVT, TVT Exact, and TVT-O procedures and review of a vast body of clinical literature.

It is incorrect to assume physicians have no understanding of the properties of mesh. In her Report, Dr. Kenton cites to the American Urogynecologic Society (AUGS) Resident Learning Objectives, noting that residents are "expected to be familiar with synthetic foreign body materials, as they should 'understand the vital characteristics of synthetic grafts, e.g. pore size, mono versus polyfilament, material types; understand the relative indications for, and complications associated with, each category of grafts; and understand the management of graft complications, both surgical and non-surgical.'" Expert Report at 4. Citing to AUGS, SUFU, and International Urogynelogical Association materials, Dr. Kenton offers opinions that TVT mesh is large pore, lightweight, monofilament, polypropylene, and an Amid Type 1 mesh, which is the material studied most and shown the best clinical results. *Id.* at 30-34.

Dr. Kenton is not going to offer opinions on the exact chemical makeup of the polypropylene used in TVT, the contents of the antioxidant package, or the suppliers of the polypropylene for TVT. Her alleged lack of qualifications on these narrow topics is irrelevant to

her ability to opine on the safety and efficacy of the TVT device based on her clinical experience and the clinical literature and data regarding the body's reactions to the TVT device.

Finally, Plaintiffs attack Dr. Kenton's statement that she has been involved in design. In doing so, Plaintiffs ignore Dr. Kenton's testimony that although she was not formally contracted as a consultant on design of transvaginally placed mesh products, she has informally participated in the design process. Ex. A, Feb. 18, 2016, Deposition of Dr. Kenton ("Feb. 18 Depo.") at 182:13-184:11. In fact, Dr. Kenton holds a patent on a suture management device for abdominal sacral colopopexy. *Id.* at 182:18-23. Clearly Dr. Kenton does have design experience, in addition to her experience as a surgeon and educator.

Dr. Kenton is well qualified to offer opinions on the safety and efficacy of the TVT device, including the clinical implications of certain physical properties of the device, and Plaintiffs' motion should be denied.

2. Dr. Kenton is qualified to offer opinions regarding the safety of mechanical-cut TVT devices, and such opinions are based on reliable evidence.

Similarly, Plaintiffs' argument that Dr. Kenton is not qualified to proffer opinions on the differences, or lack thereof, between mechanical-cut and laser-cut mesh is likewise meritless. As addressed above, Dr. Kenton is an experienced surgeon, highly qualified to offer opinions on the clinical data and outcomes regarding the impact of mechanical- and laser-cut mesh when implanted. Dr. Kenton is a fellowship trained urogynecologist who has a master's degree from the University of Michigan in Clinical Research Design and Statistical Analysis.

Plaintiffs also argue that Dr. Kenton bases her opinion on unreliable evidence, attempting to suggest that Dr. Kenton's opinions are based solely on one study comparing TVT-O to a laser-cut device made by another manufacturer. Plaintiffs mischaracterize Dr. Kenton's testimony and miss her actual opinion completely. Dr. Kenton does not opine that based upon this one study

there is evidence that there is no difference between mechanical- and laser-cut mesh. Instead, Dr. Kenton, based on her extensive and regular review of clinical literature and outcomes in her own clinical practice, states that there is *no* reliable clinical data showing that there is *any* difference between the two.

Dr. Kenton has "significant experience with both mechanically and laser cut sling mesh." Expert Report at 6. Based on such experience, she states, "Similar to the large body of published clinical outcomes data – including over 100 RCTs, TVT long-term studies, TVT-O long-term studies, Cochrane Reviews, Registries, Meta-Analyses and Systematic Reviews – I have not found any clinically relevant differences in the design properties or outcomes suggesting clinically significant differences between mechanically cut and laser cut TVT or TVT-O." *Id.* Dr. Kenton's experience includes not only general patient data from her high volume practice, but well-documented and tracked data from her design, participation in, and peer-reviewed publications based on extensive clinical studies, including the TOMUS study. *Id.* at 5.

When pressed on whether she tracked outcomes in her own clinical experience based on mechanical- or laser-cut mesh, Dr. Kenton noted that she has not specifically tracked that, but provided that it would be easy to assess outcomes of mechanical- versus laser-cut in her practice, because she first practiced at one institution using only mechanical-cut TVT and later switched to an institution using only laser-cut, and saw no difference in success rates or complications. Ex. B, Fed. 19, 2016 Deposition of Dr. Kenton ("Feb. 19 Depo.") at 231:11 – 233:2.

This makes for an easy comparison of outcomes, and Dr. Kenton has seen no differences based on the cut. Dr. Kenton's opinion is also based on her regular review of medical literature, during which she has seen nothing to suggest "that mechanically cut mesh is inferior or causes complications" or that "laser cut is superior and causes fewer complications." Expert Report at

11. Although she has seen internal Ethicon documents suggesting hypothetical problems, these theories are "not substantiated in the peer-reviewed literature" or in Dr. Kenton's patient retention rates. *Id.* at 12.

Dr. Kenton does cite to one 2006 study comparing laser cut mesh from another manufacturer's product, Obtape, to Ethicon's mechanically-cut TVT-O. *Id.* at 11. However, unlike Plaintiffs' attempt to characterize this reference in their Motion, Dr. Kenton is far from relying on this study as her only support for her opinions. As explained in the portion of the deposition quoted in Plaintiffs' Motion, Dr. Kenton only included this study because it was "the only one that's out there." Feb. 19 Depo. at 229:16-19.

As further explained by Dr. Kenton, "[t]here are very few data about actually mechanically-cut versus laser-cut, and this is about as good as the data is going to get." *Id.* at 427:7-15. But Dr. Kenton is not saying the lack of data means that she is relying solely on this 2006 study. In fact, if Plaintiffs had included the page of deposition testimony they left out between these two statements, it would show that Dr. Kenton specifically stated, "I make my decisions not based on a little itemized study but, rather, on the multitude of the outcome data. . . . There is no data to support that there is a difference [between mechanically- and laser-cut TVT-R], and there is a propensity of data to support the mechanically-cut TVT is safe." *Id.* at 428:4 – 429:2.

It is clear that Dr. Kenton does not base any opinions on one single study. Dr. Kenton bases her opinions on mechanical- and laser-cut TVT on a multitude of clinical research and her own extensive experience. None of these present any evidence of clinically relevant differences in the design properties or outcomes suggesting clinically significant differences between

mechanically- and laser-cut mesh. Dr. Kenton's testimony is based on reliable methods and a variety of data. As such, Plaintiffs' Motion should be denied.

3. Dr. Kenton's opinion that post-operative chronic pain is a rare complication with the TVT device is based on sound methodology and should be admissible.

Plaintiffs move to exclude Dr. Kenton's opinion that chronic pain is a rare complication of the TVT device implantation, arguing that this opinion is based on her "personal opinion" and is contradicted by clinical data. Again, Plaintiffs' argument must fail. Dr. Kenton's opinion is far from being based on mere "personal opinion." As a premier surgeon in the field, Dr. Kenton's personal experience, which includes over 1,250 TVT, TVT-Exact, and TVT-O implantations as well as extensive clinical study of the devices, does itself provide an adequate basis for Dr. Kenton's opinion. This Court has recognized that a physician may testify that complication rates found in literature are verified by her personal experience. *See, e.g. Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert applied reliable methodology supporting the opinion that product was safe and effective where the opinion was based upon "minimal complications in his clinical practice" which was "on par with the findings of [the] studies he cites throughout his expert report"); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12, 36 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan "by way of his experience with the Uphold device and his review of the relevant scientific literature" to opine how these procedures compare). Like the opinions in these cases, any opinions provided by Dr. Kenton based on her personal practice are buttressed by her extensive review of medical

literature and ample citations to clinical data supporting her opinion that chronic pain is a rare complication. For example, in her Report, Dr. Kenton states,

> Post-operative chronic pain and dyspareunia are rare complications associated with both the retropubic and transobturator midurethral sling (Schimpf M. SGS 2014). In a randomized trial of 565 women undergoing TVT or transobturator sling, only 2% of those undergoing TVT reported any pain beyond 6-weeks after surgery. Pelvic pain and dyspareunia are common conditions among the general population, even for women who haven't undergone pelvic surgery, and have also been reported in the medical literature for traditional procedures. (Mathias S. ACOG 1996; Jamieson DJ. ACOG 1996; Glatt AE. ACOG 1990; Laumann EO. JAMA 1999; Ozel B. Int Urogyn J 2005; Barber MD ACOG 2002).

Expert Report at 16. Dr. Kenton cites to the 2015 AUA Monograph to suggest that prolonged pain occurred in only 1% of patients with midurethral slings. *Id.* at 18-19. She cites to a Kaiser Permanente analysis finding that excision due to pain occurred in 0.04% (1 of 2,339) of retropubic midurethral slings and 0 of 794 in the transobturator group. *Id.* at 20. These are only some of the citations in her Report. *See also id.* at 20, 26, 37. Dr. Kenton's opinion is based in sound methodology and is admissible.

Plaintiffs also argue that the opinion is inadmissible because "episodes" of chronic pain are reported in Level 1 literature. Rule 702 does not require that all published data be in complete agreement on a topic. Interpretation of the data is one reason experts are required. Just because Dr. Kenton's opinions are not based on the studies or data preferred by Plaintiffs or come to the preferred conclusion of Plaintiffs does not mean the testimony is inadmissible. Furthermore, the existence of "episodes" of pain does not on its face even contradict Dr. Kenton's testimony that such episodes are rare. At best, Plaintiffs' challenge Dr. Kenton's testimony as inconsistent or weak compared to their interpretation of the data. These arguments, however, go to the weight of Dr. Kenton's testimony, not the admissibility, and are not appropriate for Plaintiffs' Motion. *See Daubert*, 509 U.S. at 596. Dr. Kenton's opinions,

whether or not Plaintiffs agree with them, are based in sound methodology and admissible. Plaintiffs' Motion to exclude them should be denied.

4. Dr. Kenton's opinions regarding the "Blaivas" article that she was shown in her deposition are based in sound methodology and are admissible.

Plaintiffs argue that Dr. Kenton cannot offer any opinions on the Blaivas article because she had not read the article. It is important to note that Dr. Kenton did not mention the Blaivas article in her report, she merely answered questions in her deposition when Plaintiffs' counsel brought up the article. Feb. 19 Depo. at 243:2-244:1. Once questioned about it, however, all testimony provided by Dr. Kenton on the Blaivas article was based on her review of it on the spot and her familiarity with and previous review of the Blaivas article source material. *Id.* at 283:4-285:12, 293:23-295:7. To the extent Dr. Kenton was commenting on the source material, whether or not she had previously read the Blaivas article is irrelevant. Because Dr. Kenton's testimony was based on extensive review of medical literature, including Blaivas article source material, it is based on sound methodology.

B. Dr. Kenton has not offered "contradictory opinions" and Plaintiffs fail to state any basis for exclusion of such alleged contradictory opinions based on admissibility.

Finally, Plaintiffs vaguely argue that Dr. Kenton cannot testify at trial in any way that "contradicts, backtracks from or counters" opinions she proffered at depositions – then mischaracterize her deposition testimony in an attempt to show how her trial testimony must be limited. Pltfs. Memo. at 13-15. To the extent Ethicon understands Plaintiffs' argument, it is not a proper basis for a motion to exclude testimony under Rule 702 – at most it is an issue that goes to the weight of the expert's testimony, not admissibility. In any event, Dr. Kenton has not, in fact, offered contradictory testimony. Plaintiffs' attempts to limit it to their preferred interpretation is without merit.

First, even assuming that a single statement from Dr. Kenton's March 25, 2016 deposition, as described by Plaintiffs, contradicted or otherwise limited previously-stated opinions, Plaintiffs do not give any reason to exclude it. Under the two-part test for admissibility of expert testimony under Rule 702 established by the Supreme Court, testimony is admitted if it "rests on a reliable foundation and is relevant." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, *2 (S.D. W. Va. Apr. 28, 2016) (quoting *Daubert*, 509 U.S. at 597). Plaintiffs have not attacked Dr. Kenton's testimony on the basis of either its foundation or relevancy, but only due to its allegedly contradictory nature. As previously noted by this Court, "Contradictions in testimony should be addressed on cross-examination." *Id.* at *9 (quoting *Daubert*, 509 U.S. at 596). Any alleged inconsistencies or weaknesses in Dr. Kenton's testimony go to its weight, not its admissibility. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attaching shaky but admissible evidence."). In short, Plaintiffs failed to show any reason why Dr. Kenton's testimony is inadmissible, and, as such, Plaintiffs' Motion must fail.

Second, contrary to what Plaintiffs mistakenly suggest, Dr. Kenton's testimony on March 25, 2016, does not contradict or limit opinions stated in previous deposition testimony or her Reports. Plaintiffs list a number of "limitations" that they argue must be imposed on Dr. Kenton's testimony at trial due to her purported contradictory or limiting testimony at her March 25, 2016, deposition. *See* Pltfs' Memo. at 13-15. None of these "limitations" should be imposed, as addressed below:

Plaintiffs' suggested "limitation"	**Dr. Kenton's actual testimony demonstrating no contradiction or reason to "limit" her trial testimony**
Limit Dr. Kenton's opinion that both TVT and TVT-O have a good safety and efficacy profile.	Dr. Kenton testified that data from the TOMUS study indicated a "slightly higher cure of stress incontinence with the retropubic." Ex. C, March 25, 2016 Kenton Depo. ("March Depo.") at 8:14-16. This statement is hardly contradictory to an overall opinion that both TVT and TVT-O have a good safety and efficacy profile for treatment of stress incontinence in women. The fact that different devices may show slightly different outcomes in different cases is not incompatible with an opinion that they are both safe devices. Dr. Kenton has provided sound methodology and support for her opinions about the safety of TVT and TVT-O which are discussed at length in her expert reports.
Dr. Kenton removed dozens of TVT-O devices.	Dr. Kenton acknowledged that she has removed TVT-O devices – but this does not discount Dr. Kenton's opinions on safety and efficacy, and, in fact, may help inform such opinions. Dr. Kenton's testimony remains consistent with previous testimony, for example where she stated, "All surgical procedures are associated with risks and complications. The complications associated with TVT and TVT-O are acceptably low and consistent across the vast body of level 1 medical literature. Just because a patient experiences a complication does not mean that TVT is defective." Expert Report at 15.
Limit Dr. Kenton's opinions that Ethicon knew its TVT-O devices were safe.	To say that Dr. Kenton was "unaware of any clinical trials conducted by Ethicon, itself, to assess the safety of its TVT-O devices," (Pltfs. Memo. at 15), is a gross mischaracterization of Dr. Kenton's testimony, which has remained consistent. On March 25, 2016, Dr. Kenton testified: Q. Okay. Do you know of any clinical trials that have been done to assess specifically the safety of the TVT-O device made by Ethicon? A. So, a clinical trial by definition is comparative. You can't really do a randomized controlled trial to look at safety because, fortunately, most of these

	complications are rare. So, most of the clinical trials are designed to look at efficacy with safety endpoints. And then it brings us to the systematic reviews and meta-analyses where we use, fortunately, validated outcome measures that we can try to compile those to more objectively look at safety. March Depo. at 22:11-24. As her testimony shows, Dr. Kenton did not testify that she was "unaware of clinical trials" assessing safety, as Plaintiffs argue, but instead she responded that one cannot really do a clinical trial to look at safety. As she testified, having a study with a primary endpoint of safety would be unethical. This was a misleading question and Plaintiffs are trying to mischaracterize Dr. Kenton's response to their liking. Furthermore, Dr. Kenton's testimony was completely consistent with previous testimony. For example, in February, she testified, "In general, you're never going to have a primary endpoint of safety for doing a randomized controlled trial in something that has a rare outcome because you would have to enroll millions – like thousands of women. So, usually you have to – you primary on an efficacy outcome." Feb. 19 Depo. at 229:5-10.
Dr. Kenton does not know with certainty if complications are caused by the TVT-O devices itself or the anatomical space where they are inserted, rendering speculative opinions that complications are due to the location in the body, not the device.	Again, this is a fundamental mischaracterization of Dr. Kenton's testimony. Throughout her testimony, Dr. Kenton states that she believes the problem to be with the space in which TVT-O is implanted, not the device. In the testimony quoted by Plaintiffs in their motion, Dr. Kenton states, "I think that there are unique complications associated with the transobturator *route of sling placement* . . . ." March Depo. at 24:12-15 (emphasis added). Just a few more lines down from this, she again clarifies "It's the route of access more than I think it's the device, like that particular trocar." *Id.* at 25:13-16. In fact, Plaintiffs' counsel acknowledged this understanding of Dr. Kenton's testimony: Q. So, what you're saying with the

	TVT – some of the unique complications, and we can get to what those are, but those unique complications with the obturator procedure, you think are more related to the route of access through the obturator space than the actual trocar itself causing the injury. A. Correct. March Depo. at 25: 17-23. To say that Dr. Kenton's testimony only the page before contradicted this immediate clarification and, therefore, limits the remainder of her testimony, is disingenuous at best.
It is a "good idea" for the FDA to reclassify mesh instrumentation to Class II.	Dr. Kenton is not offering opinions about the FDA.
A flaw with TVT-O is there is no good method to tension it properly and tensioning problems could be due to a TVT-O design flaw.	Dr. Kenton did not testify that tensioning was a flaw with the TVT-O device and/or could be due to the design. In the portion of testimony cited by Plaintiffs, Dr. Kenton stated, "I think that one of the limitations of *all* continence procedures is how do I decide how [] tight to make it for you that you can void freely and not have stress incontinence. . . . And I think that that's uniform across all continence procedures. . . ." March Depo. 38:19-2 (emphasis added). Plaintiffs' statement that Dr. Kenton was referring to TVT-O only is incorrect.
"Mesh in the pelvic region causes complications, in and of itself, which are not related either to surgical approach or to the location in the body where the implant is placed." Pltf. Memo. at 14-15 (citing Kenton Dep. at 58:16-19).	Again, Plaintiffs have mischaracterized Dr. Kenton's testimony. Here is the entire quote, in context: Q. And that mesh in the whole pelvic region, that can cause certain complications for women, correct? A. Correct. Q. And, so it seems to me that what this study is suggesting is that the complications that are related to the TVT-O either are related to the surgical route of implantation *or* the use of mesh. And all I am asking is do you agree with me that those are two different – A. Yes.

	March Depo. at 58:16-59:2 (emphasis added). Dr. Kenton's testimony, in context, shows that she simply agrees that complications can be due to either of the two causes (surgical approach or the use of mesh), not to an unrelated cause, as Plaintiffs suggest.
A flaw in the TVT-O studies is that the study period is too short.	Dr. Kenton has not testified that a short study period is a flaw in the study of TVT-O. Plaintiffs have taken Dr. Kenton's testimony out of context in this statement. When asked if more long-term evaluation should be done, Dr. Kenton actually stated, "I think we actually have good medium-term data at about five years. But, yes, we need to follow women for longer periods of time." March Depo. at 82:20-83:2. Dr. Kenton's interest in continuing to gather data by no means equates to a suggested flaw in the current TVT-O studies. Furthermore, Dr. Kenton acknowledged the difficulties of gathering long-term data. Specifically, Dr. Kenton noted that it is proven that it is difficult to get women to participate in a study for 10 or 20 years, particularly when they are happy with their medical outcomes, and it hard to otherwise gather data. *Id.* at 83:8-85:16.
Burch and autologous facial sling procedures are appropriate alternatives to TVT-O and do not carry the same risks of leg and groin pain.	Although Dr. Kenton testified that Burch and Autologous Slings are appropriate alternatives to TVT-O, she expanded much further than Plaintiff's summary on the different risk-benefit profiles of the procedures. *See, e.g.* March Depo. at 101:8-23. Dr. Kenton has extensive experience performing Burch and Autologous Slings as well as synthetic midurethral slings, such as TVT and TVT-O in both mechanically cut and laser cut, and she has published her clinical results as an investigator in the TOMUS and SISTEr multicenter prospective RCTs funded by NIH. Dr. Kenton has also published similar findings. Most recently, Dr. Kenton assisted the ACOG Committee on Practice Bulletins with the November 2015 ACOG Practice Bulletin # 155, which found that: • Synthetic midurethral slings demonstrate efficacy that is similar to traditional suburethral fascial slings, open colposuspension, and laparoscopic colposuspension. Compared with suburethral fascial slings, fewer adverse events have been reported with

	synthetic midurethral slings. Voiding dysfunction is more common with open colposuspension than with synthetic midurethral slings. • There are substantial safety and efficacy data that support the role of synthetic mesh midurethral slings as a primary surgical treatment option for stress urinary incontinence in women. Ex. D, *Urinary Incontinence in Women*, The American College of Obstetricians and Gynecologists Practice Bulletin Summary No. 155, November 2015, at 1121.
The Instructions for Use ("IFU") for TVT and TVT-O devices fail to distinguish between the unique complications and risks for each device and the TVT-O IFU did not warn of the risk of chronic leg pain.	Contrary to Plaintiffs' suggestion, Dr. Kenton identified differences in the IFUs for TVT and TVT-O – for example, that the TVT-O IFU warns of leg pain - and offers testimony that the risk for chronic leg pain was low and well known by surgeons performing these procedures. March Depo. at 135:16-136:8.

Plaintiffs' attempts to shape Dr. Kenton's testimony to their liking are misplaced in this motion. Dr. Kenton's admissible testimony must speak for itself and be weighed by the tier of facts. Furthermore, Dr. Kenton has not tried to offer new, additional, or contradictory opinions. Most importantly, Plaintiffs fail to offer any argument as to why any of the above testimony of Dr. Kenton is inadmissible under the *Daubert* standards. As such Plaintiffs' motion should be denied.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiffs' motion to exclude the testimony of Dr. Kenton.

Respectfully Submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 1 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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